

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/416,735	ATENCIO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne-Marie Falk, Ph.D.	1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 3/17/05.
2. ☒ The allowed claim(s) is/are 5-7, 21-31, and 33-37.
3. ☒ The drawings filed on 02 February 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).


\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
|---|---|

  
**ANNE-MARIE FALK, PH.D**  
**PRIMARY EXAMINER**

### Examiner's Amendment

The amendment filed March 17, 2005 has been entered. Claims 5, 22, and 35 have been amended. Claim 37 has been newly added.

Claims 5-7, 21-31, and 33-37 remain pending in the instant application.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Chris Ullsperger on May 31, 2005.

The application has been amended as follows:

#### In the Claims:

5. A method of increasing the infectivity of a cell to a viral vector by treatment of the cell with a micro-calpain inhibitor wherein said method is practiced *ex vivo*, and wherein said method comprises selecting a cell whose infectivity is to be increased, and ~~co-administering~~ co-administering said micro-calpain inhibitor and said viral vector to said cell.

35. The method of claim 5 wherein said method is practiced in a process to purge tumor cells from a stem cell product by exposing said stem cell product to a micro-calpain inhibitor prior to the administration of a viral vector.

37. A method of infecting a human cell with a virus, comprising:

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contacting said cell *ex vivo* with an amount of a micro-calpain inhibitor sufficient to increase the infectivity of said cell to said virus; and ~~co-administering~~ co-administering said virus to said cell.

The following is an examiner's statement of reasons for allowance:

The response filed March 17, 2005 addresses all objections and rejections set forth in the Office Action of March 25, 2004. The objection to the specification is withdrawn in view of the amendment to page 20 of the specification. In view of the amendments to the specification and submission of the Sequence Listing in paper form and computer readable form, the application is now in compliance with the sequence rules.

The rejections of Claims 5-7, 21-31, and 33-36 under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments to the claims and the arguments presented in the response. The rejection of Claims 5-7, 21-31, and 33-36 under 35 U.S.C. 102(b), as being anticipated by Claudio et al. (1996) is withdrawn in view of the amendment to the claims, which now recites contacting the cell with a viral vector. The rejection of Claims 5-7, 21-31, and 33-36 under 35 U.S.C. 102(b), as being anticipated by Potter et al. is withdrawn in view of the amendment to the claims, which now recites contacting the cell with a viral vector.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Upon entry of the foregoing amendment, Claims 5-7, 21-31, and 33-37 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER